NOV - 9 2004

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This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92

The assigned 510(k) number is: _____

Contact Person: Donna A. Crawford
Director, Corporate Regulatory Affairs
Mentor Corporation
201 Mentor Drive
Santa Barbara, CA 93111

Telephone: 805-879-6304
FAX: 805-879-6015

Date Prepared: June 6, 2003

Device Name and Classification

Proprietary Name:	Mentor ObTape™ Trans-obturator Surgical Kit
Common Name:	Pubourethral Support Sling
Classification Name:	Surgical Mesh, polymeric
Class:	Class II
Product Code:	OTN
CFR #:	§878.3300

Device Description

The Mentor ObTape Trans-obturator Surgical Kit consists of two components: the Mentor ObTape Trans-obturator Tape and a set of Introducer Needles.

The Mentor ObTape Trans-obturator Tape is an implantable, suburethral, support tape indicated for the surgical treatment of all types of stress urinary incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency. The tape is made from non-woven polypropylene fibers. This structure gives the ObTape resistance to traction, allows tissue colonization and facilitates positioning during surgery.

A set of sterile, disposable Introducer Needles (one flat curved introducer and a pair of helical introducers) necessary for implantation of the tape are also included in the Kit.

Substantial Equivalence Claim

The Mentor ObTape Trans-obturator Surgical Kit is substantially equivalent in material, function, performance and design to the Mentor ObTape Trans-obturator Tape and Introducers which were cleared under 510(k) K031767.

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Indications for Use

Mentor ObTape Trans-obturator Surgical Kit is indicated for the surgical treatment of all types of stress urinary incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Summary of Testing

The tape included in the Mentor ObTape Trans-obturator Surgical Kit is identical to the Mentor ObTape which was cleared under 510(k) K031767.

Mechanical testing of the sterile introducers showed that the introducers met all established criteria for mechanical performance. Biocompatibility testing on the sterile, disposable introducers demonstrated that the introducers are non-toxic and a non-irritant.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Donna A. Crawford
Director, Corporate Regulatory Affairs
Mentor Corporation
201 Mentor Drive
SANTA BARBARA CA 93111

SEP 28 2012

Re: K042851
Trade/Device Name: Mentor ObTape™ Trans-obturator Surgical Kit
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTN
Dated: October 14, 2004
Received: October 20, 2004

Dear Ms. Crawford:

This letter corrects our substantially equivalent letter of November 9, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K042851

Indications for Use

510(k) Number (if known): K042851

Device Name: Mentor ObTape™ Trans-obturator Surgical Kit

Indications For Use:

The Mentor ObTape Trans-obturator Surgical Kit consists of an implantable, suburethral support tape and introducers. It is indicated for the surgical treatment of all types of stress urinary incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or sphincter deficiency.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042851